

### Remarks

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

Claims 1-20 have been canceled without prejudice, and claims 21-44 have been added. Consequently, claims 21-24 are currently pending and under consideration.

In item 2 of the Office Action, it was stated that "[n]o claim for domestic priority has been made for the parent applications of prior Application No. 09/542,040." The applicant's representative is somewhat confused by this statement and request clarification, especially since the Filing Receipt for this application (as well as public PAIR) appears to have recognized the entire claim of domestic priority, including for the parent applications of Application No. 09/542,040. As is stated in the first paragraph of the application as originally filed "U.S. Patent Application Serial No. 09/542,040 filed March 31, 2000, now U.S. Patent No. 6,464,649, ... is a continuation of U.S. Patent Application Serial No. 09/285,021 filed April 1, 1999, now U.S. Patent No. 6,066,103, which is a continuation of U.S. Patent Application Serial No. 08/975,978 filed November 21, 1997, now U.S. Patent No. 5,964,718." Since the requirements for obtaining domestic priority are believed satisfied and the Filing Receipt acknowledged the entire chain of domestic priority, it is believed that no further action is required on the applicant's part to perfect the claim of domestic priority.

The specification has been amended in order to correct the informalities cited in items 3 and 4 of the Office Action. No new matter has been added.

In response to the informalities of the claims cited in items 5-11, it is believed that the new claims correct the cited informalities. It is submitted that the new claims are supported by the application as originally filed.

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New independent claim 21 has been added to vary the scope of protection for the features recited in previous dependent claim 5. Since the only grounds in the Office Action for rejecting claim 5 were based on obviousness type double patenting rejections, it is believed that claim 21 and its dependent claims are novel and non-obvious over the references of record.

New independent claim 29 has been added to vary the scope of protection for the features recited in previous dependent claim 6. Since the only grounds in the Office Action for rejecting claim 5 were based on obviousness type double patenting rejections, it is believed that claim 29 and its dependent claims are novel and non-obvious over the references of record.

New independent claim 33 has been added to vary the scope of protection for the features recited in previous dependent claim 4. In item 13 of the Office Action, previous dependent claim 4 was "rejected under 35 U.S.C. §103(a) as being unpatentable over Lange et al." (U.S. Patent No. 5,554,166 hereinafter referred to as "the Lange '166 patent")<sup>1</sup>. It should be appreciated that the lancet device in the Lange '166 patent does have components capable of performing all of the features recited in claim 33, and the Lange '166 patent further fails to provide any motivation to do so. For example, the lancing device in the Lange '166 patent is not capable of "expressing body fluid from the incision by depressing the tissue surrounding the incision progressively closer to the incision with the device" as recited in claim 33.

Initially, it should be recognized that the lancing device 1 in the Lange '166 patent does not depress tissue surrounding an incision in a progressively closer manner or even mention expressing fluid with the device. Further, the Lange '166 fails to provide any motivation to express fluid in such a manner. In item 13, it was alleged, "that the steps of the instant method would inherently be required to use the apparatus of Lange et al. in order to obtain a body fluid sample from an incision." Inherency

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<sup>1</sup> It should be noted that two "Lange" patents have been cited in the present application, U.S. Patent Nos. 5,318,584 and 5,554,166. It has been assumed '166 patent was the basis for the rejection in the Office Action. Even if the '584 patent was the basis for the rejection, the same analysis equally applies.

"may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999) (citing Continental Can Co. v. Monsanto Co., 948 F2d 1264, 1268 (Fed. Cir. 1991)). Even assuming for the sake of argument that the blood lancet device in the Lange '166 patent could perform the steps in the manner claimed, such steps are not inherent because they are not a necessary consequence of the '166 patent's disclosure. For instance, it is conceivable that lancet device 1 in the '166 patent could simply be used to lance the skin and not express fluid from the incision. For example, the fluid from the incision might not be expressed at all, or could be expressed with another device. Thus, the steps recited in claim 1 are not necessarily present in the Lange '166 patent, and consequently, would not be inherent in the Lange '166 patent. For this and other reasons, it is submitted that independent claim 33 and its dependent claims are novel and non-obvious over the references of record.

New independent claim 37 has been added to vary the scope of protection for the features recited in previous independent claim 9. Since the only grounds in the Office Action for rejecting claim 9 were based on obviousness type double patenting rejections, it is believed that claim 37 and its dependent claims are novel and non-obvious in view of the references of record.


In items 14-27, a number of the previous claims were rejected on the basis of obviousness type double patenting in view of the patents cited therein. Since new claims have been added, so as to not unduly limit the term of any patent issuing from the present application, the applicant has not submitted a terminal disclaimer at this time. If warranted, the applicant will consider submitting a terminal disclaimer in the future. Nevertheless, if after reviewing the present response, the Examiner finds that the only reason for rejecting the claims is due to obviousness-type double patenting, the Examiner is invited to contact the undersigned by telephone so that a terminal disclaimer can be promptly submitted, if needed, so as to speed up the allowance of the application.

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It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully Submitted,

By 

Charles P. Schmal, Reg. No. 45,682  
Woodard, Emhardt, Moriarty, McNett &  
Henry LLP  
Bank One Center/Tower  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
(317) 634-3456

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